Paper No. 40

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT BARTLETT, and JOHANN THEN

Appeal No. 2003-1138
Application No. 09/101,672

ON BRIEF

Before SCHEINER, MILLS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

An oral hearing in this case was scheduled for May 7, 2002. Upon reviewing the case, however, we have determined that an oral hearing will not be necessary and we render the following decision based on the record. See 37 CFR § 41.47(f).

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 12, 15-17, 20-26 and 29. Claim 12 is representative of the subject matter, and is drawn to:

A solid composition comprising:
a first component comprising 5-methyl-4'-trifuoromethyl-4-isoxazolecarboxanilde;
a second component comprising a compound of formula I (having a defined formula)
or a stereoisomeric form of the compound of formula I, or a physiologically tolerated salt of the compound of formula I; and
a third component comprising a pharmaceutically tolerated excipient;
wherein the first component has a concentration from about 2 to about 20 mg and the second component has a concentration from about 0.8% to about 15% of the first component.

Claim 12 is attached as Appendix I.

The examiner relies upon the following reference:

Bartlett et al. (Bartlett)	4,965,276	Oct. 23, 1990

Claims 12, 15-17, 20-26 and 29 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bartlett.[1] After careful review of the record and consideration of the issues before us, we reverse.

DISCUSSION

According to the rejection, Bartlett teaches a pharmaceutical composition that is useful in the treatment of chronic graft-versus-host disease and autoimmune diseases such as systemic lupus erythematosus. See Examiner's Answer, page 3. The composition contains as the active ingredient at least one compound of formula 1 or formula 2. See id. The rejection notes that the compound of Formula 1 of the Bartlett patent "embraces the first component of the composition of the instant claims," and that the "[t]he compound of formula 2

of the Bartlett [ ] patent is analogous to formula I of the second component of the instant claims." Id.

The rejection notes that "[t]he composition of the instant claims may differ from the compositions disclosed in the Bartlett [ ] patent by disclosing the first and second components together as one composition." Id. The rejection concludes:

> However, it is noted that the utility for the composition comprising formula 1 and 2 of the Bartlett [ ] patent are the same, that is, both compounds are used to treat chronic graft-versus-host diseases and autoimmune diseases such as systemic lupus erythematosus. Case law, In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980), states that it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose, which is what Appellants have done. The composition of the instant claims further disclose that the first component has a concentration from about 2 to about 20 mg and the second component has a concentration from about 0.8% to about 15% of the first component. However, the concentration of first and second components does not make the claims patentable over the Bartlett [ ] patent since case law states that synergism may be expected or unexpected (Synergism exhibited by a physical mixture of ingredients is a factor to be considered in determining the obviousness of the composition but it is not controlling since synergism may be expected or unexpected. In re Hullmantel, CCPA 1963) 324 F2d 998, 139 USPQ 496; Ethyl Corp. v. Ladd. Comr. Pats. (DCDC 1963) 221 F Supp 751, 138 USPQ 663. . . . In re Vaeck, 947 F.2d 488, 492, 20 USPQ 2d 1438, 1441 (Fed. Cir. 1991) states that for an invention to be obvious, two things must be found in the prior art: (1) the suggestion of the invention, and (2) the expectation of its success. In the instant case, both 1 and 2 are satisfied by the combination of the teachings of the Bartlett [ ] patent and the pertinent case law. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Appellants invention having the Bartlett [ ]

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[1] We note that the Examiner's Answer set forth three grounds of rejection, rejecting claims 12 and 15-17 over Bartlett, claims 20-26 over Bartlett and claim 29 over Bartlett. As all three grounds of rejection are essentially the same, we analyze all three grounds of rejection at once.

> patent before him to obtain the instantly claimed invention in view of the analogous structures of the compounds disclosed in the compositions and the resulting expectation of similar therapeutic properties.

Id. at 4.

Appellants argue that Bartlett does not teach all of the elements of the claimed invention. According to appellants, the claims require a combination of compounds 1 and 2, "wherein compound 2 is present at a concentration of about 0.8% to about 15% of compound 1. Compound 1 may be present from about 2 mg to about 20 mg. As a result, the maximum concentration of compound 2 is about 3 mg (i.e., about 15% of about 20 mg)." Appeal Brief, page 7.

Bartlett, appellants contend, teaches away from the claimed concentrations. See Appeal Brief, pages 8-14. Bartlett teaches that "solid forms of compound 1 and/or 2 may be present at '10 to 200 mg, but preferably 50 to 100mg,'" and also provides the activity of the of compound 1 tested at 5, 10, 20 and 28 mg, and the activity of compound 2 tested at 20 and 30 mg, but does not test the activity of compound 1 and compound 2 together. Id. Bartlett, appellants assert, does not test the activity of compound 2 below 20 mg. See id.

Appellants assert in fact that:

> In Table 1, Bartlett discloses that 5 and 10 mg/kg of compound 1 have almost zero effect (less than 5%). At 20 mg/kg of compound 1, only a 28% inhibition was reported. In fact, 28 mg/kg of compound 1 was required to achieve any appreciable biological effect. In Table 2, both 5 and 10 mg/kg of compound 1 again show less than a 5% effect. It required 20 to 28 mg/kg of compound 1 to achieve any appreciable level of activity. Table 3 similarly indicates that compound 1 only works at concentrations of 20 mg/kg or higher.

Id. at 10. Appellants contend that these results would motivate one of ordinary skill in the art to use larger amounts of compound 1, rather than the lower amounts, i.e., about 2 mg to 20 mg, required by the instant claims.

With respect to compound 2, appellants assert that:

> Bartlett provides experimental data testing concentrations of 20 or 30 mg/kg (See Table 2). At 20 mg, compound 2 achieved a 33% reduction in disease severity. At 30 mg of compound 2, a 56% reduction is reported. No lower concentrations of compound 2 are ever described. As with compound 1, Bartlett teaches that as the concentration of compound 2 increases, the composition is more effective. Clearly, such teachings would motivate one of skill in the art to use higher amounts of compound 2 (i.e. greater than 20 mg) to achieve an effective result. There would be absolutely no motivation to use the lower concentrations of compound 2 recited in the present claims, which do not exceed about 3 mg.

Id. at 10-11.

We agree with appellants. "A rejection based on section 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, all facts must be considered. The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. To the extent the Patent Office rulings are so supported, there is no basis for resolving doubts against their correctness. Likewise, we may not resolve doubts in favor of the Patent Office determination when there are deficiencies in the record as to the necessary factual bases supporting its legal conclusion of obviousness." In re

Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. Denied, 389 U.S. 1057 (1968) (emphasis in original).

In the case before us, the claims require that "the first component has a concentration from about 2 to about 20 mg and the second component has a concentration from about 0.8% to about 15% of the first component." As set forth by appellants arguments, even if we assume, arguendo, that Bartlett suggests a composition comprising both compounds 1 and 2 of Bartlett, Bartlett teaches away from using lower the concentrations of those compounds as required by the claims.

The examiner appears to be of the opinion that the concentration of components 1 and 2 as required by the claims would be obvious over the teaching of Bartlett "since it is recognized in the art that synergism may be expected or unexpected." Examiner's Answer, page 6 (citing In re Huellmantel, 324 F.2d 998, 139 USPQ 496 (CCPA 1963) and Ethyl Corp. v. Ladd, 221 F.Supp. 751, 138 USPQ 663 (D.D.C. 1963). In those two cases, however, as asserted by appellants, one of the components of the composition was known to have improved properties. See Reply Brief, pages 4-7. The examiner has pointed to no evidence that would have led the ordinary artisan to a composition comprising components 1 and 2 as set forth in the instant claims having the claimed concentrations, and the rejection is reversed. See In re Lee, 277 F.3d 1338, 1343-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (in reviewing an

obviousness rejection, the court noted that "conclusory statements" as to teaching, suggestion or motivation to arrive at the claimed invention "do not adequately address the issue.").

CONCLUSION

Because the rejection fails to set forth a prima facie case of obviousness, it is reversed.

REVERSED

Toni R. Scheiner)
Administrative Patent Judge)
)
)
Demetra J. Mills) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
Lora M. Green)
Administrative Patent Judge)

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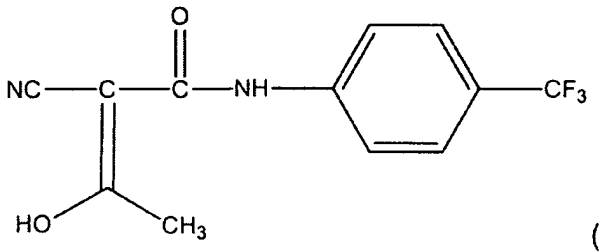
Appendix I

12. A solid composition comprising:

a first component comprising 5-methyl-4'-trifluoromethyl-4-isoxazolecarboxanilide;

a second component comprising a compound of formula I



(I)

or a stereoisomeric form of the compound of formula I, or a physiologically tolerated salt of the compound of formula I; and

a third component comprising a pharmaceutically tolerated excipient;

wherein the first component has a concentration from about 2 to about 20 mg and the second component has a concentration from about 0.8% to about 15% of the first component.